Abstract

A study using two different and parallel information sources or methods was carried out with the purpose of assessing the reactogenicity of the Cuban diptheria-tetanus-Pertussis vaccine, developed at Finlay Institute. The first was an open, non-controlled Phase IV Clinical Assay (CA) in which 57 small babies were included. The second information source was the reports of the vaccine temporally associated events (VTAE) received at the National Pharmaceutical Surveillance Coordinating Unit (NPSCU) which includes 86 babies examined for VTAE suspicion. In the CA, 167 vaccine doses were administered. Expected and unexpected adverse events were observed in a very small number of babies and were mainly mild and limited in time. Their frequency of appearance was reduced for the second and third doses. Pain was the most frequent local event and fever, the most frequent general one. Vomiting was not reported and anorexia, drowsiness and persistent crying appeared in a small number of vaccinated subjects. Twelve unexpected events occurred, only two of them were considered to be causally related to the vaccination. One severe adverse event was reported. A girl was hospitalized with a severe prolonged post-vaccination fever syndrome. It was found to be a persistent urinary sepsis caused by a vesico-ureteral malformation. The 86 reports received at the NPSCU included 141 VTAE. Among the local symptoms erythema reached 9.3% and induration, 5.81%. Fever was a frequent symptom although the body temperature was not reported. Although there are different ways for carrying out the surveillance for adverse events in a CA or in routine clinical practice, these results confirm that vaccine reactogenicity is scarce when compared to the benefits of its use in small babies.

Keywords

Reactogenicity, adverse events, cuban DTP vaccine.